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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,861	12/12/2001	Neil S. Cutshall	240083.514	2603

500 7590 09/04/2002

SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 6300
SEATTLE, WA 98104-7092

EXAMINER	
DESAI, RITA J	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 09/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/015,861	CUTSHALL ET AL.	
	Examiner	Art Unit	
	RITA J. DESAI	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) *17 and 31-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,13 and 16* is/are rejected.

7)☒ Claim(s) *5-12,14,15 and 18-30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4 &5* .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-16, 18-30 , drawn to compounds and pharmaceutical compositions wherein R2 is a Hydrogen , R3 is an aryl or an aryl alkylene, classified in class 546, 514, subclass 347, 358.

II. Claims 1-28, 30 , drawn to compounds and compositions wherein R 2 and R3 are other than in Group I, classified in various classes and subclasses. A further election of a single disclosed species is required.

III. Claims 31-44 , drawn to methods of treating diseases using these compounds , classified in class 514 , subclass 358.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions I and II have different groups attached to the pyridine N-oxide, that they have a different bonding , and structure.

A preliminary search on the core resulted in numerous iterations indicating that the core was not applicants novel contribution over the prior art.

Inventions I,II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case thesre are various other known drugs used to treat diseases such as arthritis, or cancer.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I, is not required for Group II or III , restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Carol Roth on 8/29/2002 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-16, 18-30 all in part drawn to compounds and compositions wherein R2 is a Hydrogen , R3 is an Aryl. Affirmation of this election must be made by applicant in replying to this Office action. Claims 17, 31-44 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

Claims 4 and 12 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claims, since claim 1 is drawn to the elected group , then claim 4 and 12 will not further limit the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16, 18-29 recites the limitation "that the phenyl group is substituted" in claim 1 there is no definition of the substitution nor the substituents on the aryl or arylalkylene groups. There is insufficient antecedent basis for this limitation in the claim 1.

Claim Rejections - 35 USC § 102

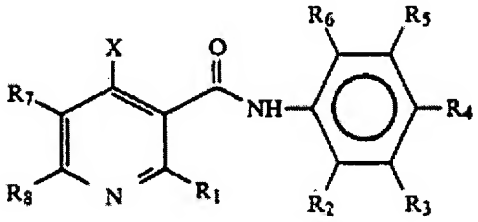
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 9 –11 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4978385 Hiroshi Yagihara et al. (EP292990)

Hiroshi '385 discloses the N-Oxides of the claim 1.

See formula I,



(I)

r the 1-oxide or a salt thereof,

The reference discloses numerous N-oxides on column 5 , and table 1

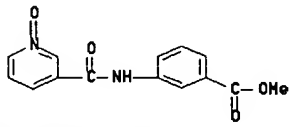
TABLE 1

Example No.	R_1	R_2	R_3	R_4	R_5	R_6	R_7	R_8	X	mp (°C.)	Method
1	CH_3	C_2H_5	H	CH_3	H	C_2H_5	CH_2=CH—CH_2—	CH_3	Cl	192.5-194	A
2	"	"	"	H	"	"	"	"	"	200-204.5	"
3	"	"	"	Cl	"	"	"	"	"	145.5-148	"
4	"	"	"	Br	"	"	"	"	"	201-203	"
5	"	"	"	H	"	"	HC≡C—CH_2—	"	"	242-244	"
6*	"	"	"	Cl	"	"	CH_2=CH—CH_2—	"	"	187.5-188.5	C
7	"	"	"	I	"	"	"	"	"	222-224	A
8	"	"	"	Br	"	"	n-C_4H_9	"	Cl	228.5-229	A
9	"	H	"	H	"	H	H	"	"	157-158	"
10	"	CH_3	CH_3	"	"	"	C_2H_5	"	"	193-197	"
11	"	C_2H_5	H	"	"	C_2H_5	H	"	"	210.5-215	"
12	"	"	"	"	"	"	CH_3	"	"	222-229.5	"
13	"	"	"	"	"	"	C_2H_5	"	"	232-232.5	"
14	"	"	"	"	"	"	n-C_3H_7	"	"		"
15	"	"	"	"	"	"	iso-C_4H_9	"	"	162-164.5	"
16	"	"	"	"	"	"	iso-C_5H_{11}	"	"	196.5-198	"
17	"	"	"	"	"	"	Br	"	"		"
18	"	"	"	"	"	"	Ph	"	"	210-211	"
19	"	"	"	"	"	"	CH_2Ph	"	"	213.5-215.5	"
20	C_2H_5	"	"	"	"	"	CH_3	"	"		"
21	n-C_3H_7	"	"	"	"	"	H	"	"		"
22	"	"	"	"	"	"	CH_3	"	"		"
23	n-C_4H_9	"	"	"	"	"	H	"	"		"
24	"	"	"	"	"	"	Br	"	"		"
25	CH_3	"	"	"	"	"	CH_3	C_2H_5	"	244-246	"

This compound reads on the instant wherein R1 is an alkyl, R4 is a halogen or alkyl or aryl. See examples 8 on wards.

Claims 1, 2, 4, 13, 16,are rejected under 35 U.S.C. 102(b) as being anticipated by Caplus English Abstract N 131:237346 , title Possibilities for search for new analgesics in the series of arylamides of isonicotinic and nicotinic acids Bukhtiarova, T. A et al

The abstract discloses compounds of the formula

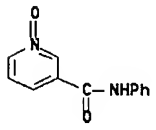


See RN# 6510144-2.

This reads on the compounds of the invention wherein R1 is a hydrogen , n is 0, R2 is hydrogen, R3 is substituted.

Claims 1,2,4 are rejected under 35 U.S.C. 102(b) as being anticipated by Caplus English Abstract DN 75:75600, title Intramolecular hydrogen bond. IV. The ir spectra of N-oxides of anilides of pyridinecarboxylic acids, Mirek, Julian et al (1971), 45(2), 205-9

The reference discloses compounds of the formula



See RN # 14178-43-9.

This reads on the compounds wherein R1 is a hydrogen n is o, R2 is hydrogen and R3 is an aryl.

Conclusion

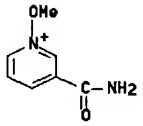
The claims 1,2, 4,13, 16 are not found to be allowable.
The other claims are are objected to since they are based on a rejected claim.

Closest Prior Art:-

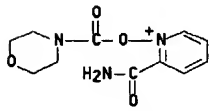
Caplus English abstract DN 81:169412

Reactions of N-alkoxycyclimmonium salts. I. Pentadiene derivatives from

N-alkoxypyridinium salts Schnekenburger, Joerg et al (1974), teaches the pyridinium salts amino salts but they do not have an aryl group for a Hydrogen.



US 4055427 teaches



but again the amido group is at the 2- position and also amino hydrogen is not replaced by an aryl group!

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RITA J. DESAI whose telephone number is 703-305-1868. The examiner can normally be reached on Monday - Friday,9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

R.D.
September 3, 2002